2M8063 FLO-GARD 6201 INFUSION PUMP REPAIR SPEC, JCAHO CERTIFICATION, PREVENTIVE MAINTENANCE CHECK LIST

1.0 Purpose

This is a recommended procedure for customers to verify proper operation of a 2M8063, FLO-GARD 6201 Infusion Pump after repair. This procedure is also for customers and Baxter field service personnel for preventive maintenance checks. This may also be used to comply with JCAHO recommendation of safety and performance testing.

If any failures are found during this inspection, the device should be repaired prior to placing it back into service.

2.0 Equipment

- Hemostat (Optional)
- Stopwatch or timer calibrated to range of 0-15 min. with a resolution of at least 1 second
- Balance or scale with resolution of 0.1 g calibrated to at least a range of 0 to 500 g.
- ASTM Class A 25 mL graduated cylinder with increments of 0.2 mL tc (to contain)
- Baxter standard S-Suffix set such as 2C5545s with the new (dark blue) slide clamp design
- Occlusion calibration thickness gauge (Part No. UKOG1013.B)
- Safety analyzer which can accurately measure ground resistance of 0.5 ohm and current leakage of 50 microamps
- Gas Tight Syringe (Part No. S9662-81)
- 20 gauge needle (Part No. S9670-1) or catheter
- Old style (light blue) slide clamp (Part No. 020416132)
- E-ring remover
- New style (dark blue) slide clamp (Part No. 030216490)

3.0 Calibration Verification and Display Tests

3.1 Calibration Verifications In Mode 1

With the device powered OFF, press and hold both CLEAR TOT VOL and "1" keys simultaneously, then press the ON/OFF CHARGE key (both CLEAR TOT VOL and "1" keys must remain pressed for at least 3 seconds). Place the occlusion calibration thickness gauge (Part No. UKOG1013.B) alternately in the upstream and downstream occlusion sensors of the pump with the device connected to AC power. (Multiple gauges can be used at the same time.)

1. Upstream Occlusion
   Verify the value displayed in the PRI RATE location (upper left of pump's main display). Value must be 3242 to 3314. Record value and check PASS or FAIL on the data sheet.

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2. Downstream Occlusion
Verify the value displayed in the PRI VTBI location (lower left of pump's main display). Value must be 2967 to 3039. Record value and check PASS or FAIL on the data sheet.

3. Main Battery
Verify the value displayed in the SEC RATE location (upper right of pump's main display). Value must be 688 to 714. Record value and check PASS or FAIL on the data sheet.

4. Backup Battery
Verify the value displayed in the SEC VTBI location (lower right of pump's main display). Value must be 574 to 737. Record value and check PASS or FAIL on the data sheet.

3.2 Calibration Verifications In Mode 2

With the device powered OFF and connected to AC power, press and hold both CLEAR TOT VOL and "2" keys simultaneously, then press the ON/OFF CHARGE key to access Test Mode 2. (Both CLEAR TOT VOL and "2" keys must remain pressed for at least 3 seconds).

1. NORM and MIN Air Sensor Calibrations With Primed Tubing:
Load a primed tubing segment such as 2C5545s, spliced into the middle of an S-suffix set, into the pump head and close the door. Open and close the pump head door two more times and wait 2 minutes for the readings to stabilize. View the NORM value displayed in the PRI RATE location (upper left of pump's main display). Next, view the MIN value displayed in the PRI VTBI location (lower left of pump's main display). **Both** values must be 330 to 565. Record values and check PASS or FAIL on the data sheet.

2. NORM and MIN Air Sensor Calibrations With Air Filled Tubing:
Remove the primed tubing and load an unprimed calibration tubing segment and close the door. Open and close the pump head door two times and wait 2 minutes. View the NORM and MIN air sensor values. **Both** values must be less than 11. Record values and check PASS or FAIL on the data sheet.

3. NORM and MIN No Tube Air Sensor Values
Remove the empty tubing and close the door. View the NORM and MIN air sensor values. **Both** values must be less than 40. Record values and check PASS or FAIL on the data sheet.

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4. Right and Left Force Sensing Resistor (FSR) Voltage
View the value displayed in the SEC RATE location (upper right of pump's main display). View the value displayed in the SEC VTBI location (lower right of pump's main display). **Both** values must be 500 to 820. Record values and check PASS or FAIL on the data sheet.

3.3 Display Check In Mode 5

With the device powered OFF, press and hold both CLEAR TOT VOL and "5" keys simultaneously, then press the ON/OFF CHARGE key (both CLEAR TOT VOL and "5" keys must remain pressed for at least 3 seconds). Verify that all segments appear. Check PASS or FAIL on the data sheet.

Note: All the LCD segments, LEDs and icons turn on sequentially for a visual check each time the STOP key is pressed. At any point in the sequence the SEC START key may be pressed to return to the beginning of the sequence.

4.0 Standard Functional Tests

4.1 Software Version

With the pump powered OFF, press and hold the SILENCE key, then press the ON/OFF CHARGE key.
Record the software version number displayed in the secondary VTBI display on the data sheet.

4.2 Self Test

With the device disconnected from AC power and the device powered OFF, press the ON/OFF CHARGE key to power it ON. Then verify that:

1. AT BEGINNING OF SELF TEST:

- All LEDs turn on. All segments of the message display and all segments of the main display must turn on. All backlighted icons are turned on except for the plug icon.
- The main buzzer will turn on and change tone while all segments of the displays are on.
- The backup buzzer will turn on after the main buzzer turns off.
- When the backup buzzer turns off, all LEDs will turn off.

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2. DURING SELF TEST:

- The main display remains off until the end of self test.
- The message display sequence is as follows:

Hospital Area Designator - if device is configured with options 1-9),
OCCLUSION LEVEL 1, 2, or 3
AUDIBLE SWITCHOVER if configured ON,
and then AUTO RESTART if configured with options 1-9, and FLOW CHECK if configured ON.

Note: Options configured in the pump will determine what may appear on the display during self test.

3. AT THE END OF SELF TEST:

- The main display should show the following:

PRI RATE (ML/HR)
0
PRI VOLUME (ML)
TO BE INFUSED
0

Non zero PRI and/or SEC rates and VTBIs may appear if still retained in the five hour memory.

- The message display should show the following:

STOPPED

- BATTERY LOW alarm must not be activated.
- Battery icon must be lit.
- Reconnect the device to AC power. Verify that the plug icon is lit and that the battery icon is OFF.
  Leave the device connected to AC power whenever possible.

Check PASS or FAIL on the data sheet.

4.3 Record the Configuration

Enter the Review Configuration mode.

1. Power ON the device.
2. Press the TIME and TOT VOL STATUS keys simultaneously and hold for 1 second.
3. The Message display should show "REVIEW CONFIG".
4. If the device does not show the above message, repeat step 2 above.

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5. Continue to press the NEXT or SEC START key to scroll through the options and record the options on the data sheet.
6. Verify that the configuration is set as required by user facility. See the Service Manual for listed default settings or for changing the configuration.

4.4 Door Open Sensor

1. Power the device OFF then back ON with the pump head door closed.
2. Open the pump door after the self test.
3. Verify that the alarm LED is active and that the display message states "DOOR OPEN". "CLOSECLAMP" may also appear depending on the configuration. The audible alarm will not sound unless the door is opened while the pump is running.
4. Check PASS or FAIL on the data sheet.

4.5 Slide Clamp Mechanism

Note: This section is to be performed only if the slide clamp feature is enabled and the slide clamp spring retainer has been removed. If the slide clamp feature is not enabled, proceed to Section 4.6 below. If the slide clamp feature will be enabled for the first time, refer to the Disassembly and Calibration section in the pump's Service Manual to configure the slide clamp option.

A set with the new style (dark blue) slide clamp (Part No. 030216490) compatible with the slide clamp mechanism should be used in this section.

1. With the device powered ON, fully insert the slide clamp of a primed set into the slide clamp slot, and load the set into the pump mechanism.
2. Close the pump door to release the latched mechanism.
3. Open door. Press the safety clamp arm and verify that it will not lock in the open position. Try to pull the slide clamp out and verify that the slide clamp cannot be removed.
4. Push the slide clamp in fully. Verify that the safety clamp arm can be latched in the open position, and that the slide clamp and tubing can be removed.
5. Load the primed set again but do not insert the slide clamp into the mechanism. Close the door. Verify that "INSERT SLIDECLAMP" is displayed with the alert or alarm LED (depending on software version and configuration) constantly ON, and the audible tone alternately ON and OFF.
6. Open the pump door and remove the tubing from the device. Check PASS or FAIL on the data sheet.

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4.6 Air Alarm Test

Use Primary rates only. Set PRImary VTBI greater than 1000 mL. Using distilled or tap water that has been adequately degassed, introduce the specified air bubble with a precision gas tight syringe and manipulate the tubing or bubble so that the air bubble is just below the pumping mechanism and above the air sensor before starting the pump.

Perform either of the NORM or the MIN test below depending on the configuration setting.

1. NORM Configuration Setting Test:

   If the AIR SIZE configuration parameter is NORM, perform the following test sequence.

   Inject a 110 microliter air bubble and start the pump at 125 mL/hr. The pump must go into an air alarm and stop. Check PASS, FAIL, or N/A on the data sheet.

2. MIN Configuration Setting Test:

   If the AIR SIZE configuration parameter is MIN, perform the following test sequence.

   Inject an 85 microliter air bubble and start the pump at 125 mL/hr. The pump must go into an air alarm and stop. Check PASS, FAIL, or N/A on the data sheet.

4.7 Upstream & Downstream Occlusion Test

1. Upstream
   Program the pump for a rate of 200 mL/hr and an adequate VTBI. Start the pump. Let the pump deliver at least 5 mL without alarm. Then occlude the tubing 12 to 16 inches above the pump and start calibrated stopwatch or timer. Verify that an upstream occlusion alarm occurs and the pump stops pumping within 3 minutes. Check PASS or FAIL and record time for upstream occlusion alarm to occur on the data sheet.

2. Downstream
   Remove the occlusion upstream. Start the pump. Occlude the tubing below the pump. Verify that an occlusion alarm occurs and the pump stops pumping. Check PASS or FAIL on the data sheet.

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4.8 Accuracy Check

Load a S-suffix set such as 2C5545s primed with water in the pump head. Mark the section of tubing in the pumping mechanism to prevent future reuse of the same segment.

Use one of the following techniques to measure the flow delivery:

If the pump passes the test, record the Method Used (1, 2, 3, or 4), the value obtained, and check PASS on the data sheet. Also, check "N/A" on Section 4.9 (1 HOUR TEST) on the data sheet to show that the 1 hr test was not performed. Proceed to Section 4.10.

If the value falls outside of the range, check "Utilized 1 Hour Test" on the data sheet and perform Section 4.9.

1. Measurement by weight per time:

   Program a VTBI of at least 500 mL and start the pump at 200 mL/hr. Collect the solution in a container of known weight for 10 minutes and 30 seconds, ± 3 seconds. Then using a calibrated scale with a resolution of 0.1 g or better, weigh the container and solution. Then divide the solution weight by the specific gravity of the solution (water's specific gravity is 1 g/mL). The solution collected should be between 32.5 mL and 37.5 mL.

2. Measurement by volume per time:

   Program a VTBI of 20 mL and start the pump at 200 mL/hr. Collect the solution in an ASTM Class A 25 mL graduated cylinder, with a resolution of 0.2 mL or better, for 6 minutes ± 3 seconds or until the pump switches to the KVO mode. It is important to stop the pump within 10 seconds after the KVO alert, since fluid delivered after the KVO alert adds to the test error. The solution collected should be between 18.6 mL and 21.4 mL.

3. Measurement by time per volume:

   Program a rate of 200 mL/hr and a VTBI greater than 35 mL. Measure the time within 3 seconds that it takes to collect 35 mL ± 0.2 mL. Calculate the flow rate in mL/hr by dividing 35 mL by the measured time converted to hours. Note that the Dynatec Model 404A Flow Analyzer can be used for this method. The flow rate should be between 186.0 and 214.0 mL/hr.

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4. Measurement incorporating VTBI option:

   Program a rate of 200 mL/hr and VTBI of 35 mL. Start the pump and collect the solution in a container of known weight. When the pump goes into KVO alert mode, stop the pump within 20 seconds. It is important to stop the pump within 20 seconds after the KVO alert, since fluid delivered after the KVO alert adds to the test error. Then, using a calibrated scale with a resolution of 0.1 g or better, weigh the container and solution. Then divide the solution weight by the specific gravity of the solution (water's specific gravity is 1 g/mL). The solution collected should be between 32.5 mL and 37.5 mL.

4.9 One Hour Accuracy Test (optional)

1. Load an S-suffix set such as 2C5545s primed with water. Ensure that the loaded tubing segment is new and un-used. Program a primary rate of 125 mL/hr with a VTBI of 1000 mL.
2. Place the distal end of a set into a container of known weight. Unit should be connected to AC power.
3. Simultaneously start a timer and push the START key. After one (1) hour ± 20 seconds stop the pump. The water collected should weigh between 116.25 g and 133.75 g.
4. **If the pump passes this test, check "PASS" on Section 4.9 (1 HOUR TEST) on the data sheet and record the value obtained.**
5. If the collected weight is not within 116.25 g to 133.75 g, check "FAIL" on "1 HOUR TEST" on Section 4.9 of the data sheet and verify proper test technique. This test is not to be rerun to obtain better results unless there is a reason to believe the test technique was in error. Pumps that fail this accuracy test are to be serviced.

4.10 Lock Out

With the pump powered ON, program a VTBI of at least 500 mL. Load a primed set, and start the pump with a rate of 200 mL/hr. Press the LOCK OUT button on the back panel and verify that the "Loc" message appears. All keys should not be accessible except BACK LIGHT and TOT VOL STATUS. Press the LOCK OUT button again and verify the "Loc" message disappears. Check PASS or FAIL on the data sheet.

4.11 Pump Mechanism Free Flow Prevention

1. Use a head height of 27 inches or higher. This is measured from the middle of the pump mechanism to the top of the solution level.

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2. Load the tubing into the pump head properly. Open all roller and slide clamps to allow free flow. Close the pump door and observe the distal end of the set for at least 60 seconds. No more than one half (1/2) mL of fluid (5 maxidrips or 30 minidrips) is allowed in the first 60 seconds. No gravity flow is allowed after 60 seconds. Check PASS or FAIL on the data sheet.

4.12 FSR Function

Check the operation of the FSR by performing the following:

1. Power ON the pump.
2. Open the door and misload the tubing over the left FSR.
3. Close the door.
4. Verify that the message display shows "CHECK SET LOADING", the ALARM LED is ON alternately, and the audible alarm tone is sounding.
5. Open the door and misload the tubing over the right FSR.
6. Close the door.
7. Verify that the message display shows "CHECK SET LOADING", the ALARM LED is ON alternately, and the audible alarm tone is sounding.
8. Check PASS or FAIL on the data sheet.

4.13 Alarm Volume

Induce an alarm. Turn the alarm sound volume knob clockwise and counterclockwise. Verify that the sound volume increases as the volume knob is turned clockwise to the limit, and that the sound volume decreases as the volume knob is turned counterclockwise to the limit. The alarm/alert sound should be audible when the volume knob is in any position. Check PASS or FAIL on the data sheet.

Note: Release the device with the volume control in the loudest position.

4.14 Battery Operation

Disconnect the pump from AC power. Load a primed set and start the pump at 1901 mL/hr with a VTBI of 160 mL. Verify that the battery icon is lit and that the unit runs for at least 160 mL or 5 minutes. If a battery low alert or alarm occurs, refer to the Battery Check section in the service manual or replace the battery if there is reason to believe that it is damaged/degraded. Check PASS, FAIL, or REPLACED BATTERY on the data sheet.

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5.0 Electrical Safety Tests

5.1 Ground Impedance

Perform a ground impedance test. The ground impedance must not exceed 0.1 Ohm using a 25 Amp ROD-L Ground Impedance Tester per UL 544 or 0.5 Ohm using an equivalent NFPA-99 tester. Record the result and check PASS or FAIL on the data sheet.

5.2 Current Leakage

Perform a leakage current test per UL 544. The leakage current for this device must not exceed 50 microamps. Record the result and check PASS or FAIL on the data sheet.

6.0 Visual Inspection

Visually inspect the pump to ensure that no physical damage has occurred. Check to be sure that all labels and feet are firmly attached. Check PASS or FAIL on the data sheet.

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INSPECTION DATA SHEET 1 of 2 (This may be reproduced)

SERIAL NO. _____
COMMENTS_____

P=Pass, F=Fail, N/A=Not Applicable

3.0 Calibration Verification and Display Tests

3.1 Calibration Verifications In Mode 1

1. UPSTREAM.....(3242 to 3314)...Value: ( )P ( )F
2. DOWNSTREAM.....(2967 TO 3039)...Value: ( )P ( )F
3. MB (688 to 714).....Value: ( )P ( )F
4. BB (574 to 737).....Value: ( )P ( )F

3.2 Calibration Verifications In Mode 2

1. NORM AND MIN Air Sensor Calibrations With Primed Tubing
   NORM.....(330 to 565).....Value: ( )P ( )F
   MIN.....(330 to 565).....Value: ( )P ( )F
2. NORM AND MIN Air Sensor Calibrations With Air Filled Tubing
   NORM.....(<11).....Value: ( )P ( )F
   MIN.....(<11).....Value: ( )P ( )F
3. NORM AND MIN No Tube Air Sensor Values
   NORM.....(<40).....Value: ( )P ( )F
   MIN.....(<40).....Value: ( )P ( )F
4. Right and Left Force Sensing Resistor (FSR) Voltage
   Right FSR..(500 to 820).....Value: ( )P ( )F
   Left FSR...(500 to 820).....Value: ( )P ( )F

3.3 Displays

Display check in Mode 5.....( )P ( )F

4.0 Standard Functional Tests

4.1 SOFTWARE VERSION..._____

4.2 SELF TEST.....( )P ( )F

4.3 RECORD THE CONFIGURATION:

First Line	Second Line	First Line	Second Line
CLR ALARM	N/A	BAUD RATE	300 1200 2400
OCCLUSION LEVEL	1 2 3		4800 9600
AUDIB SWI	OFF ON	COMP CONT	DISABLED OFF W ALRM
AUTO RES (0-9)	_____		ON W ALRM
DOOR OPEN	OFF ON	HAD	0 or _____
AIR SIZE	NORM MIN	CLOSE CLMP	OFF ON
ALARM INT (1-7)	_____	INS CLAMP	OFF ON or ALERT ALARM
ALERT INT (1-7)	_____	PDP	DISABLED FIVE HOUR
MAX RATE (1-1999)	_____		SEMI PERM PERM RAMP PDP
MAX VTBI (1-9999)	_____	TIME	N/A
FLOW CHECK	OFF ON	DATE	N/A

SIGNATURE: DATE:

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INSPECTION DATA SHEET 2 of 2 (This may be reproduced)

SERIAL NO. _____
COMMENTS_____

P=Pass, F=Fail, N/A=Not Applicable

4.4 Door Open Sensor.....( )P ( )F
4.5 Slide Clamp.....( )P ( )F
4.6 NORM AIR ALARM UPPER LIMIT(110 μL).....( )P ( )F ( )N/A
MIN AIR ALARM UPPER LIMIT(85 μL).....( )P ( )F ( )N/A
4.7 OCCLUSION TESTS
Upstream Occlusion.....( )P ( )F
Time for Upstream Occlusion alarm to occur....[mins sec]
Downstream Occlusion.....( )P ( )F
4.8. ACCURACY CHECK..(Circle method #: 1 2 3 4)
Value: _____.....( )P ( )Utilized 1 Hour Test
4.9 1 HOUR TEST (optional) Value: _____.....( )P ( )F ( )N/A
4.10 LOCK OUT.....( )P ( )F
4.11 PUMP MECHANISM FREE FLOW PREVENTION.....( )P ( )F
4.12 FSR FUNCTION.....( )P ( )F
4.13 ALARM VOLUME.....( )P ( )F
4.14 BATTERY OPERATION...(5 min).....( )P ( )F ( )REPLACED BATTERY

5.0 Electrical Safety Tests

5.1 GROUND IMPEDANCE..____Ohms.....( )P ( )F
(≤ 0.1 Ohm per UL 544 or ≤ 0.5 Ohm per NFPA-99)
5.2 CURRENT LEAKAGE (≤ 50) [_____]Ua ( )P ( )F

6.0 Visual Inspection.....( )P ( )F

SIGNATURE: DATE:

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